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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,725	03/19/2004	Charles L. Armstrong	38-21(52947)	2724

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MONSANTO COMPANY
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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/708,725

Applicant(s)

ARMSTRONG ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 and 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date October 13, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-5 and 11-18) in the reply filed on February 13, 2006 is acknowledged. The traversal is on the ground(s) that a search for all groups would not create a burden on the Examiner. This is not found persuasive because as stated in the Office Action mailed December 2, 2005 a search of all the groups together would require different key word searches of each group using divergent patent and non-patent literature databases and subsequent in-depth analysis of the unrelated prior art literature (see page 3, for example).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6-10 and 19-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 13, 2006.

Claims 1-5 and 11-18 are under examination.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 11 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for corn, does not reasonably provide enablement for any type of plant. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification only provides evidence of the claimed methods being used with corn (see page 39, Example 1; page 44, Example 2; page 46, Example 3; page 48, Example 4; page 52, Example 7, for example).

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The use of *Agrobacterium* mediated transformation is unpredictable.

Zhao et al (Molecular Breeding 8:323-333, 2001) teach that various factors can affect the efficiency *Agrobacterium* mediated transformation in plants, such as the *Agrobacterium* strain used and the type of vectors that are used in the transformation (see page 323, 2nd column, 2nd paragraph to page 324, 1st column, 1st paragraph) and that plant genotypes have a large impact on transformation results (see page 330, 2nd column). Zhao et al also show factors such including antibiotics, plant culture media, *Agrobacterium* concentration, co-cultivation duration, and resting period need to be balanced against one another to achieve an overall high level of transformation (see page 330, 2nd column, 2nd paragraph).

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Hansen et al (Trends in Plant Science 4(6): 226-231, 1999) teach that plant transformation is not an exact science, but more of an art because of the unique culture conditions required for each crop species and that to accommodate a species that has not been manipulated in culture previously one must either adapt an established protocol or create a new one, bearing in mind the efficiency imperatives (see page 230, 2nd column, 1st paragraph).

Given the unpredictability of the art, it would require undue trial and error experimentation for one skilled in the art to make and use the invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (U.S. Patent Application Pub. No. US 2002/0188965, December 12, 2002), in view of Jia (U.S. Patent 5,770,788, June 23, 1998).

The claims read on a method of obtaining a transformed dihaploid plant comprising obtaining haploid sporophytic tissue, transforming the haploid sporophytic tissue, producing dihaploid tissue from the transformed haploid sporophytic tissue and regenerating a dihaploid plant from the dihaploid tissue.

Zhao et al teach a method of obtaining transformed maize plants comprising obtaining a haploid sporophytic tissue, namely embryos, transforming said tissue and regenerating plants from said tissue (see page 8, 1st column, paragraph 0062 to paragraph 0066).

Zhao et al do not teach producing dihaploid tissue from haploid tissue using colchicine and regeneration of said haploid tissue.

Jia teaches the use of colchicine to produce dihaploid tissue and the regeneration of a dihaploid plant from the dihaploid tissue (see Table in column 3 and column 4, lines 10-12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Zhao et al with those of Jia to produce a method of obtaining a transformed dihaploid plant.

One of ordinary skill in the art would have been motivated to combine these teachings to produce a method of obtaining a transformed dihaploid plant because Jia teaches "[d]oubled haploids offer the quickest possible approach to homozygosity [and]

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[i]t is believed that one to two years can be saved in the testing phase of a corn breeding [program] through the use of doubled haploids (see column 1, lines 61-65).

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Zhao et al in producing transformed maize plants.

8. Claims 1-5 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormann et al (U.S. Patent No. 6,316,694, November 13, 2001).

The claims read on a method of obtaining a transformed dihaploid plant comprising obtaining haploid sporophytic tissue, transforming the haploid sporophytic tissue, producing dihaploid tissue from the transformed haploid sporophytic tissue and regenerating a dihaploid plant from the dihaploid tissue.

Dormann et al teach a method of obtaining a transformed dihaploid plant comprising obtaining embryogenic microspores and transforming embryogenic microspores wherein the transformed embryogenic microspores are capable of leading to a transformed haploid or doubled haploid embryo that develops into a fertile homozygous plant (see column 2, lines 58-67). In addition, Dormann et al teach the use of colchicine as a compound to that can be used to double the haploid microspore genome (see column 4, lines 37-42).

Dormann et al do not teach obtaining haploid sporophytic tissue; however they do teach that microspore culture can induce a sporophytic pathway (see column 1, lines 22-26).

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Dormann et al to produce a method of obtaining a transformed dihaploid plant comprising obtaining haploid sporophytic tissue, transforming the haploid sporophytic tissue, producing dihaploid tissue from the transformed haploid sporophytic tissue and regenerating a dihaploid plant from the dihaploid tissue.

One of ordinary skill in the art would have been motivated to modify the teaching of Dormann et al because Dormann et al teach "[t]he time saving for the breeder working with microspore transformants compared to transformants from heterozygous plant material is estimated to be three years for the development of each transgenic variety" (see column 1, lines 29-32).

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Dormann et al in transforming embryogenic microspores into fertile homozygous plants.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

April 20, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.